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February 8, 2022

VIA CM/ECF

Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*,
No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Vanaskie:

Pursuant to the Court's request during the January 18, 2022 status conference, please accept this letter on behalf of Plaintiffs in opposition to ZHP's request to seal the entirety of Exhibit CC to ECF 1189.

The applicable law is well known to the Court, and the Court should not accommodate ZHP's repeated conclusory claims of harm tethered to generic references to internal information, the disclosure of which will not clearly cause defined harm in the present. It is also worth noting that **"the more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access."** *In re Avandia Mktg., Sales, and Prods. Liab. Litig.*, 924

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F.3d 662, 670 (3d Cir. 2019) (emphasis added) (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)).

The common law right of access “antedates the Constitution.” *Bank of Am. Nat’l Tr. & Sav. Ass’n v. Hotel Rittenhouse Assocs.*, 800 F.2d [339,] 343 [(3d Cir. 1986)]. **The right of access “promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court.”** *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access “diminishes possibilities for injustice, incompetence, perjury, and fraud.” *Id.* Moreover, “the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness.” *Id.*

* * *

[T]he public's right of access must be the starting point, not just one of multiple factors. The scale is tipped at the outset in favor of access. And **the right of access is not a mere formality**—it “promotes public confidence in the judicial system”; “diminishes possibilities for injustice, incompetence, perjury, and fraud”; and “provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness.” *Littlejohn*, 851 F.2d at 678. **These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.**

Avandia, 924 F.3d at 672, 677 (emphasis added). Moreover, **“where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality** whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law.” *Pansy v. Stroudsburg*, 23 F. 3d 772, 791 (3rd Cir. 1994) (emphasis added). Even more importantly, the Third Circuit has **“repeatedly said that concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access.”** *Avandia*, 924 F.3d at 676 (emphasis added) (collecting cases).

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As with all motions to seal, the movant must show “why a less restrictive alternative to the relief sought is not available.” Loc. R. 5.3(c)(3)(d).

On remand from the Third Circuit in *Avandia*, the trial court unsealed “55 documents—including clinical studies, GSK submissions to the FDA, internal GSK emails and letters, records of teleconferences between GSK and the FDA, Avandia presentations and plans, and some court filings in the MDL,” with the exception of “certain personal information that Plaintiffs do not object to redacting.” *In re Avandia Mktg, Sales Practices and Prods. Liab. Litig.*, 484 F. Supp. 3d 249, 264-68 (E.D. Pa. 2020) (emphasis added). The court summarized its decision in the following manner:

Justice Brandeis famously declared that “sunlight is the most powerful of all disinfectants.” Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents. Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.

Id. at 268 (emphasis added).

Third Circuit precedent similarly requires the denial of ZHP's request to ECF 1189, Ex. CC. As previously noted, this document is the final GMP inspection report from the European Medical Agency (EMA) and European Directorate for the Quality of Medicines & HealthCare (EDQM), “[REDACTED]

[REDACTED]

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[REDACTED].” (ZHP02324737). “[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].”

(*Id.*). To begin with, these subjects are all public—this scandal has been publicly evaluated and the minute details have been public for years. The idea that information from any source about this failed process that will never again be used could somehow cause present serious harm to ZHP is far-fetched at best. At most, it will buttress the already robust public record regarding ZHP’s disgraceful conduct and willful failure to prevent the sale of these contaminated drugs. To the extent this document contains information about ZHP’s manufacturing processes, “quality” controls or “testing” procedures, that information is necessary to address the above points, all of which the public has a valid and heightened interest in understanding given the worldwide contamination of ZHP’s as well as other manufacturers’ sartans and other drugs with nitrosamines. *See Avandia*, 924 F.3d at 672, 677; *Avandia*, 484 F. Supp. 3d at 264-68. Crucially, the Court cannot consider ZHP’s selfish interest in hiding its wrongful conduct (that is, the defective manufacturing processes and ineffective “quality” controls and “testing” procedures discussed in this document) when evaluating whether ZHP has overcome the presumption of the public’s right to access this document—because ZHP’s reputation or embarrassment is not a legitimate consideration. *Avandia*, 924 F.3d at 676.

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In fact, Plaintiffs obtained the FDA's inspection investigating ZHP's defective manufacturing practices via the Freedom of Information Act. (Ex. 1). In that report, ZHP explicitly admitted that it adopted the contaminating manufacturing process "to save money" and that "the cost reduction was so significant it is what made it possible for the firm to dominate the world market share." (*Id.* at 25). **The Court must consequently recognize that ZHP's misconduct in this case was primarily motivated by its desire to minimize its costs, increase its market share, and ultimately maximize its profits. Moreover, ZHP's competitors and co-defendants were incentivized to adopt similar cost-cutting measures in their efforts to compete with ZHP.** The public has a right to understand this story, and ZHP's declaration in opposition to that right is nothing but a conclusory statement that it wants to continue to shield its misconduct from the sun's disinfecting rays. The Court denied ZHP's prior motion to seal seven similar documents on May 24, 2021, and it should do so again here. ([ECF 1269](#)).

The Court has also asked whether this EMA/EDQM report is accessible via a law similar to the Freedom of Information Act. The answer is yes. According to the EMA's policy, "[i]n principle, all documents of the EU Institutions and of the European decentralised Bodies, such as the European Agencies, are accessible to the public." (Ex. 2, p. 1). "As of its establishment the European Medicines Agency (EMA) has embraced openness of operation as an important feature." (*Id.*). "Whilst providing adequate protection of commercial confidential information, personal data and other conflicting interests as identified..., access to a requested document will be denied only if one of the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 will be considered applicable." (*Id.* at p. 3). "When only parts of a document contain information that cannot be disclosed, access to the remaining parts of the document shall be granted." (*Id.*). In fact, the EMA has already publicly discussed this inspection. (EMA, *EU inspection finds Zhejiang*

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Huahai site non-compliant for manufacture of valsartan: EMA and national authorities considering impact on other active substances produced at the site (Sept. 28, 2018, <https://www.ema.europa.eu/en/news/eu-inspection-finds-zhejiang-huahai-site-non-compliant-manufacture-valsartan-ema-national>; see also Eric Palmer, *EU regulators blast China's Zhejiang Huahai over valsartan API mess* (Sept. 28, 2018), <https://www.fiercepharma.com/manufacturing/eu-regulators-blast-china-s-zhejiang-huahai-over-valsartan-api-mess>). Thus, there is no regulatory impediment to disclosure of ECF 1189, Ex. CC with the type of limited redactions found in the FDA's 2018 investigation into the same issue, precluding the Court from sealing any more than that type of narrowly circumscribed and limited information. See *Pansy*, 23 F. 3d at 791.

However, given the public's right to access this document as a court record, the public's strong interest in understanding the worldwide contamination of sartans as well as other drugs with nitrosamines, and ZHP's failure to explain with any specificity how a competitor could use this report to learn anything that is not common industry knowledge or of any use **at this time**, the Court should deny ZHP's motion to seal or redact any part of this document. See *Avandia*, 924 F.3d at 672, 677; *Avandia*, 484 F. Supp. 3d at 264-68 (**denying a motion to partially redact "55 documents—including clinical studies, GSK submissions to the FDA, internal GSK emails and letters, records of teleconferences between GSK and the FDA, Avandia presentations and plans, and some court filings in the MDL," with the exception of "certain personal information that Plaintiffs do not object to redacting"** (emphasis added)). If the Court is inclined to permit sealing of any part of this document, the law requires a granular analysis, and the narrowest redactions possible.

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Thank you for your courtesies and consideration.

Respectfully,

A handwritten signature in purple ink, appearing to read "Adam M. Slater", is written over a horizontal line.

ADAM M. SLATER

cc: All Counsel (via CM/ECF)